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June 6, 2019

The Honorable Michael Rodrigues
Chair, Senate Committee on Ways and Means
Massachusetts State House
24 Beacon St.
Room 212
Boston, MA, 02133

The Honorable Cindy Friedman
Vice Chair, Committee on Ways and Means
Massachusetts State House
24 Beacon St.
Room 413-D
Boston, MA 02133

Re: Senate Budget Outside SECTIONS 6, 61, and 95

Dear Senators Rodrigues and Friedman:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) to provide comments about SECTIONS 6, 61, and 95 of the Senate's Budget (S2235), which address the purchase of medicines by MassHealth.

Outside Sections to the Budget, SECTIONS 6 and 61 respectively, create new authority for HPC and EOHHS over drug manufacturers that greatly exceeds existing authority over any other industry in the Massachusetts health ecosystem.

Both the Governor's version and the Senate's version of the Outside Sections of the Budget regarding MassHealth Pricing treats the purchasing of drugs differently from the purchase of other MassHealth services. We are supportive of changing the law to allow direct negotiation outside of existing authority in 801 CMR 21.00. If that change is made, it is unclear why the other authorities are needed. Specifically, the Outside Sections allow the Executive Office of Health and Human Services (EOHHS) and the Health Policy Commission (HPC) new authority in connection with the pricing of drug products in MassHealth that is inconsistent with and that goes beyond the authority for purchasing other MassHealth goods and services. This language, for the first time, allows EOHHS to coerce concessions by way of punitive measures, such as referring a manufacturer to HPC and potentially the Attorney General if a certain purchase price is not achieved. This expands the role of HPC; HPC currently is not involved in the purchase of any MassHealth good or service. Further, EOHHS or HPC currently cannot request unlimited

pricing information from a seller of goods or services provided to MassHealth patients. This proposal also would establish new precedents for both EOHHS and HPC. Specifically, the proposal would allow EOHHS to set a value, and post it publicly, for MassHealth drug purchases, which it does not do for any other industry. And, the proposal would allow HPC to hold *ad hoc* public hearings in which a vendor must justify the pricing of its products or services or to determine whether a product's pricing is "unreasonable and excessive," which it does not do currently.

In addition, there is no current authority under Chapter 6D of the Chapter laws for referral of any entity (whether provider or manufacturer of goods) to the Office of the Attorney General exclusively in connection with costs charged for specific healthcare goods or services.

HPC is currently authorized to collect information from payors and providers in connection with the performance improvement plan ("PIP") process under Section 2A of Chapter 6D, but that section also lays out the confidential nature of how information is handled for entities placed under a PIP:

> Section 2A The commission shall keep confidential all nonpublic clinical, financial, strategic or operational documents or information provided or reported to the commission in connection with any care delivery or quality improvement process or performance improvement plan activities authorized under section 7, 10, 14 or 15 of this chapter or under section 2GGGG of chapter 29 and shall not disclose the information or documents to any person without the consent of the payer or provider providing or reporting the information or documents under said section 7, 10, 14 or 15 of this chapter or under said section 2GGGG of said chapter 29, except in summary form in evaluative reports of such activities or when the commission believes that such disclosure should be made in the public interest after taking into account any privacy, trade secret or anticompetitive considerations. The confidential information and documents shall not be public records and shall be exempt from disclosure under clause Twenty sixth of section 7 of chapter 4 or section 10 of chapter 66.

In contrast, new Section 8A proposed by Senate Budget Outside SECTION 6 allows HPC to compel public testimony about the pricing of a drug, which will certainly result in demands for the disclosure of commercially sensitive information; other industries are not subjected to this same treatment for the reimbursement of MassHealth services.

The new Section 8A subjects drug manufacturers to measures that bear little resemblance to how HPC treats other entities in the course of the Annual Cost Trends Hearings. The underlying cost trends data reviewed by HPC at those hearings is collected by the Center for Health Information and Analysis (CHIA), a state agency consisting of full-time state employees, and not HPC, which is comprised of private citizens from various healthcare related sectors. Many of the private citizens that comprise HPC are involved in negotiations to purchase medicines on behalf

of their employer (e.g., hospitals or insurers) from the very pharmaceutical entities that may be subject to HPC scrutiny, which raises concerns about potential misuse of information and knowledge gained while participating on the HPC (e.g., participating in the *ad hoc* pricing hearings and reviewing pricing materials from manufacturers). By ensuring that raw cost trends data is collected by CHIA, existing law ensures that potentially sensitive data are subject to confidentiality protections and that the sensitive information is only handled and used by a state agency rather than potential marketplace competitors.

What's more, under HPC's current PIP authority, HPC's deliberations on whether to subject a payor or provider to a PIP are entirely confidential—so much so that the list of entities potentially subject to the PIP is kept from public view, and the HPC may elect to meet in executive session for such deliberations.[1] Inexplicably, Outside SECTIONS 6and 61 contain no such protections for manufacturers targeted by EOHHS and HPC for supplemental rebates and unlimited drug price transparency disclosures.

In summary, the Outside Sections would grant EOHHS and HPC unlimited authority to subject manufacturers to *ad hoc* public hearings, unlimited transparency disclosure requirements, and potential action by the Attorney General based only on whether the price of a particular drug exceeds an arbitrary price limit of $25,000 per year on a per utilizer basis or $10,000,000 in post-rebate costs in the aggregate, and whether EOHHS determines without any clear direction or criteria (in particular, for example, downstream hospital costs avoided by the introduction of the targeted therapy, among other factors) that a drug is unreasonably priced. This approach appears to be based on the proposal's inherent presumption that drug costs that fit this criteria must be unreasonable and excessive. In contrast, under current law, HPC's authority to subject payors and providers to PIPs is much more considered and restrained. That is, HPC may only target entities for PIPs where their healthcare costs exceed the statutory benchmark (currently 3.1%), as determined by CHIA's data collections, for any given year. This limited authority reflects what in essence is HPC's primary function under current law—as a monitor of health care cost trends in Massachusetts and a source of policy proposals for keeping such trends in line with the statutory benchmark. In contrast, Outside SECTIONS 6 and 61 would greatly and without any apparent basis transform HPC's current authority as a collaborative monitor of heath care costs into a key participant in one of the nation's first Medicaid drug price setting and enforcement laws. Particularly where net drug costs continue to be 6.2% of MassHealth spending,[2,3] such an expanded regulatory role for HPC is inconsistent with its core mission and

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[1] See https://www.mass.gov/files/documents/2018/02/07/policy-2017-01-process-for-performance-improvement-plans-amended.pdf; see also PIP regulations at https://www.mass.gov/files/documents/2017/04/zi/958cmr10.pdf.

[2] 6.2% is extrapolated from CHIA's 2018 Annual Report.

[3] Note that the federal assistance medical percentage (FMAP) for Massachusetts is 50%, but some beneficiaries may have a higher federal match. (see https://www.govinfo.gov/content/pkg/FR-2018-11-28/pdf/2018-25944.pdf)

unfairly punitive toward drug manufacturers, that are critically important participants in the delivery of healthcare in the Medicaid program.

Finally, with respect to the Senate Budget, we believe the study created in SECTION 95 could be very informative to the Commonwealth as it takes steps to reduce pharmacy costs while balancing access to needed medicies for MassHealth recipients.

Thank you very much for meeting with us on about our concerns. We look forward to working with you as the Senate considers the MassHealth Pricing Outside SECTIONS.

Kind regards,

Leslie Wood